

Claims Rejection – 35 USC 112

Resolved by claim amendment.

Claims Rejection - 35 USC §102

The Examiner has rejected claims 38, 40, 41, 46, 50-54, 61, and 69 as anticipated under 35 USC 102(b) by Katims. The Examiner has erroneously confused the idea of an electrical stimulus, as described by Katims, with that of stimulus control therapy, as described in the current application.

Katims teaches a machine that applies an electrical stimulus to a subject suffering from a variety of neuropsychological disorders. (Katsims, Column 1 lines 13 – 15). Katims further teaches a method to optimize the amount of electrical stimulus applied to a particular subject.

Unlike Katims, the current application teaches a passive tool that allows a patient to monitor his/her wake/sleep status in conjunction with the rules of stimulus control therapy (or other behavior therapies) allowing him or her to fall asleep quickly and stay asleep. Stimulus control therapy, as used in the current application, is characterized by a set of instructional rules such as: "use the bed and bedroom only for sleep...." (Application No. 10/790,885, page 2, lines 16 - 25, and page 3, lines 1 - 9) (Bootzin Declaration, paragraphs 8, 9 and 10)

Nowhere does the current application discuss electrical stimulation. Comparing Katims with the current application is illogical.

In order to demonstrate anticipation, the Examiner must make a *prima facie* showing that the four corners of a single prior art document describe every element of the claimed invention. Xerox Corp v. 3Com Corp, 458 F3d 1310, 1322 (Fed. Cir. 2006). Further, prior art reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention. *In re Arkley*, 455 F. 2d 586 (CCPA 1972). Katims does not clearly and unequivocally disclose the claims of the current invention and therefore, the Examiner has not met this burden of showing anticipation. Consequently, Katims does not anticipate the claims cited by the Examiner.

Claim 38

The Examiner's assertion that that Claim 38 is anticipated by element 17 (column 5, line 65 through column 6, line 40) and element 12 (column 5, lines 37-45) of Katims is erroneous.

Element 17 of Katims teaches a signal transducer system, a preprocessing signal system, signal analysis system, and a computer. These systems, in combination, could be used to perform or monitor any number of differing functions (e.g. measure mass flow from a pump or translate an analog voice to a digital signal). Element 17 does not clearly and unequivocally disclose the claims of the current invention. Element 17 does not, either explicitly or implicitly, teach a system or group of systems that monitors a subject's wake/sleep state. *See Lindeman Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984). (The court held that a claim to a shearing machine was not anticipated by a prior art reference that contained all of the elements of the claimed machine "because it disclosed an entirely different device, composed of parts

distinct from those of the claimed invention, and operating in a different way to process different material differently.") Consequently, Katims does not teach the limitations of claim 38.

Even if, *arguendo*, element 17 of Katims taught a sleep/wake monitor, it still does not teach such a monitor used in combination with behavior therapy. Element 12 of Katims is an electrical simulator, which is applied to a subject (i.e. control of an electrical stimulus). This is absolutely not the same as a "means for implementing a behavioral therapy", as described in the current application. Stimulus Control does not involve the administration of a stimulus in the manner of the cited art. (Bootzin Declaration, paragraphs 8,9 and 10) Consequently, Katims does not teach each limitation of claim 38 either explicitly or implicitly and therefore, Katims does not anticipate Claim 38.

Claim 40

The Examiner mistakenly compares Element 12 (column 8, lines 57-63) to claim 40 of the current application. Element 12 (column 8, lines 57-63) discusses an electrical stimulator and electrical output control. This is further evidenced by Fig. 5, referred to in column 8, lines 57-63. Fig. 5 shows a circuit which controls an electrical stimulator. As mentioned above, the control of an electrical output is completely different from a "...means to choose a behavior therapy..." There is simply no comparing here; these are two different concepts. Element 12 (column 8, lines 57-63) does not, either explicitly or implicitly teach claim 40 and therefore, does not anticipate claim 40.

Claim 41

The Examiner's comparison of the disclosure in Katims (column 6, lines 1-7 and 41) to claim 41 of the current application is misguided. Katims, in column 6, lines 1-7, teaches a transducer system which can receive input from electrophysiological monitors. Claim 41 of the current application teaches a passive wake/sleep determination means which uses information chosen from a set of electrophysiological parameters. These two concepts are inherently different. Therefore, Column 6, lines 1-7 and 41, do not explicitly or implicitly teach claim 41.

Claim 46

The Examiner incorrectly argues that Katims, column 2, lines 4-7, anticipates claim 46 of the current invention. Katims teaches the setting of a level of electrical stimulus in order to help a subject "wake up, go to sleep, replace drugs, play a song, or a game of pinball". (column 2, lines 6-7) Claim 46 discusses optimization of a behavior therapy based on the subjects wake/sleep state information. As discussed above, behavior therapy is not electrical stimulus. (Bootzin Declaration, paragraphs 8, 9, and 10) The comparison the Examiner has made is illogical.

Claim 47

Claim 47 is not anticipated by element 17 (column 5, line 65 through column 6 line 40) and element 12 (column 5, lines 37-45) of Katims. The Examiner has made a flawed comparison.

As discussed above, element 17 (column 5, line 65 through column 6 line 40) teaches, in the most general terms, a generic system for acquiring a signal and performing some sort of signal analysis. However, unlike claim 47, Element 17 does not, either explicitly or implicitly, teach a system or group of systems that monitors a subject's wake/sleep state. *See Lindeman Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984). (The court held that a claim to a shearing machine was not anticipated by a prior art reference that contained all of the elements of the claimed machine "because it disclosed an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way to process different material differently.") Consequently, Katims does not anticipate Claim 47.

Again, even assuming *arguendo*, that Katims teaches "a determination means for producing information indicative of the subject's wake/sleep state", Katims does not clearly and unequivocally teach stimulus control therapy. As discussed above, element 12 of Katims is an electrical simulator, which is applied to a subject. This is not at all the same as a "means for implementing a behavior therapy" such as stimulus control. Stimulus Control does not involve the administration of an electrical stimulus in the manner of the cited art. (Bootzin Declaration, paragraphs 8, 9 and 10) Consequently, Katims does not teach each limitation of claim 47 either explicitly or implicitly and therefore, Katims does not anticipate Claim 47.

Claim 50

Katims does not anticipate Claim 50. As discussed above, Katims teaches electrical stimulus, which is applied to a subject. This is not the same as a "behavior therapy" such as stimulus control or sleep restriction, as discussed in Claim 50. Stimulus Control does not involve the administration of an electrical stimulus in the manner of the cited art. (Bootzin Declaration, paragraphs 8, 9 and 10) Consequently, Katims does not teach each limitation of claim 50 either explicitly or implicitly and therefore, Katims does not anticipate Claim 50.

Claim 51

Comparing Claim 51 with Column 10, 20-34 of Katims to reach an anticipation rejection is illogical. Katims, at column 10 teaches control of the electrical output from an electrical simulator. Claim 51 teaches system settings which are unrelated to electrical output; claim 51 teaches output which is related to a particular subject. Katims does not anticipate Claim 51 because Katims discloses an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a completely different manner. *Id.*

Claims 52, 53, 61,69 and 54

Katims does not clearly and unequivocally disclose Claim 52, 53, 61 or 69. Katims at column 2, lines 3-7, teaches a machine that provides electrical stimulus; when the electrical stimulus is set to optimal parameters, the machine can help the patient wake up or go to sleep.

Claim 52 teaches a behavior therapy optimized for a particular subject, based on their individual wake/sleep information, history, or a combination thereof. Katims discloses an entirely different device, composed of parts distinct from those of Claim 52, and operate in a different way to process different kinds of information. *See Lindeman Maschinenfabrik GmbH* at 1452. Therefore, Katims does not anticipate Claim 52.

Similarly, indicator lights 37 and 38 discloses devices entirely different from Claim 53, 61, and 69. Light 37 is a clipping indicator light and light 38 is a battery low indicator light. These lights indicate information about the status of the machine; they relay no information regarding the subject. Claims 53, 61, and 69 relay information about a subject's status. Katims discloses an entirely different device, composed of parts distinct from those of Claims 53, 61, and 69, and operate in a different way to process different kinds of information. *Id.*

Claim 53 teaches a means to review information the apparatus has acquired about the subject; Claim 61 gives visual/ audio instruction(s) regarding information collected about the subject to the subject; and Claim 69 provides behavioral prompts to aid the subject. That is, Claims 53, 61, and 69 provide information to adjust the subject not the apparatus. Consequently, Claims 52, 53, 61, and 69 are not anticipated by Katims.

Claim 54

Finally, Katims column 7, lines 3-17, does not anticipate Claim 54. Katims adjusts electrical current intensity depending on the subject's response; it says nothing about wake/sleep history. In fact, Katims statement can be generally related to any type

of signal generator. Claim 51 calculates the subject's sleep statistics. This is based on more than merely signal history. Again, Katims discloses an entirely different device than Claim 54. *Id.* Consequently, Katims does not anticipate Claim 54.

Claims Rejection - 35 USC §103

The Examiner has incorrectly rejected Claims 42 and 43 as being unpatentable over Katims in view of Wyatt. The Examiner argues that "The apparatus of Wyatt teaches a device as claimed but does not include additional drug therapy or active sensing means." The Examiner further argues that "Wyatt teaches that it is old and well known to use drug therapy and active sensing means for the treatment of insomnia." Consequently, the Examiner argues, "It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to include the active device and drug therapy set forth in Wyatt." The examiner has not made a *prima facie* case of obviousness.

Three basic criteria must be met to establish a *prima facie* case of obviousness under Section 103:

- (a) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference of combine reference teachings;
- (b) There must be reasonable expectation of success; and
- (c) The prior art must teach or suggest all the claim limitations.

The cited prior art has no motivation, nor would one with ordinary skill in the art have been motivated, to modify the reference or combine teachings at the time the invention was made.

Here, the scope and content of the cited prior art *teaches away* from Claims 42 and 43. Claim 42 teaches the use of drug therapy in conjunction with behavior therapy. One object of Wyatt's is to "... provide a drug-free sleep training method for the insomniac...." (Column 3, lines 15-18) Wyatt states, "For many reasons, a successful sleep training method would be preferred over drug therapy." (Column 1, lines 20 – 31). The cited prior art does not provide any motivation for one of ordinary skill in the medical arts at the time the invention was made to include a **passive** wake sleep determination used **in conjunction** with drug therapy. (Bootzin Declaration, paragraphs 14, 15 and 16)

Claim 43 teaches an active means for wake/sleep determination to supplement the passive means for wake/sleep determination. As mentioned above, Wyatt teaches a device that provides an **active** wake/sleep determination and Katsim **does not teach** any sort of wake/sleep determination. Again, the cited art does not provided any motivation for one of ordinary skill in the medical arts at the time of the invention was made to supplement passive means for wake/sleep determination with an active means for wake sleep determination and there is no reasonable expectation of success. (Bootzin Affidavit, paragraphs 14, 15, and 16)

Finally, the cited prior art does not teach or suggest all the claim limitations. Neither Katsim nor Wyatt teaches the use of **passive** wake/sleep determination. Consequently, the Examiner has not made a *prima facie* case for obviousness. Therefore, claims 42 and 43 are patentable.